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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,473	04/08/2004	Wei Chen	900.1009US	1056

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,473	CHEN ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III (claims 54-62) without traverse in response to the Office Action mailed on 10/17/2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 61 recites the

broad recitation "about 97% or greater trans-capsaicin", and the claim also recites "about 98% or greater trans-capsaicin" and "about 99% or greater trans-capsaicin" which are narrower statements of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54- 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967).

Jancso et al. teaches, "**Rats can be desensitized against chemical pain with** the repeated incremental doses of **capsaicin** ... or, ... by means of a single larger dose." (See page 140, Lines 22-24). "**Capsaicin (trans-N[4'-hydroxy-3'-methoxy-benzyl]-8-methylnon-6-enamide)** is practically insoluble in water, so the 1% solution used for desensitization was prepared with Tween 80 as follows: 0.1g crystalline capsaicin was dissolved in 2-3 drops of ethanol, to which 15 drops (about 0.6g) of Tween 80 were added." (See page 140, Lines 25-28). Jancso et al. further teaches, "Rats weighing 140-200 g were desensitized over a period of 24 hr; each rat was **injected subcutaneously** with 4, 8, and 15 mg at 6-hr intervals, or with a single does of 10-20mg." (See page 140, Lines 27-28). A trans capsaicin such as the one taught by Jancso et al. where a crystalline powder of **trans**-N[4'-hydroxy-3'-methoxy-benzyl]-8-

methylnon-6-enamide (i.e. Capsaicin) is used would inherently be an approximately 100% pure trans capsaicin because no other isomer is distinguished as being present.

It is noted that the recitation of the intended use "**treatment of nociceptive pain, neuroceptive pain, pain from nerve injury, pain from neuralgia ...**" (claim 55) and "**treatment of orthopedic disorders selected from ...**" (claim 56)has not been given patentable weight to distinguish over **Jancso et al.** because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since **Jancso et al.** discloses compounds that are the same as those claimed, they would be capable of performing the intended use, as claimed. Therefore, the reference is deemed to anticipate the instant claims above. In a claim to a composition a statement to the composition's intended use has no patentable weight since the intended use does not structurally change or add component(s) to the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Jancso et al. (British Journal of Pharmaceutical Chemotherapy, pp. 138-151, Published 1967) in view of Guenzler-Pukall et al. (US 2004/0204356 A1, Published 10/14/2004).

Applicant Claims

A pharmaceutical composition comprising trans-capsaicin comprising about 99% or greater trans-capsaicin and vehicle suitable for injection wherein the vehicle comprises about 20% PEG 300, about 10 mM histidine and about 5% sucrose in water.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Jancso et al. teaches, "**Rats can be desensitized against chemical pain with** the repeated incremental doses of **capsaicin** ... or, ... by means of a single larger dose." (See page 140, Lines 22-24). "**Capsaicin (trans-N[4'-hydroxy-3'-methoxy-benzyl]-8-methylnon-6-enamide)** is practically insoluble in water, so the 1% solution used for desensitization was prepared with Tween 80 as follows: 0.1g crystalline capsaicin was dissolved in 2-3 drops of ethanol, to which 15 drops (about 0.6g) of Tween 80 were added." (See page 140, Lines 25-28). Jancso et al. further teaches, "Rats weighing 140-200 g were desensitized over a period of 24 hr; each rat was **injected subcutaneously** with 4, 8, and 15 mg at 6-hr intervals, or with a single does of 10-20mg." (See page 140, Lines 27-28). A trans capsaicin such as the one taught by Jancso et al. where a crystalline powder of **trans**-N[4'-hydroxy-3'-methoxy-benzyl]-8-methylnon-6-enamide (i.e. Capsaicin) is used would inherently be an approximately 100% pure trans capsaicin because no other isomer is distinguished as being present.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Jancso et al. does not expressly teach using a pharmaceutical vehicle comprising polyethylene glycol (PEG 300), histidine, and sucrose. Teachings of Guenzler-Pukall et al. cure this deficiency.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Guenzler-Pukall et al. teaches, "**Suitable carriers for intravenous injection** of the invention is well known in the art and include **water-based solutions containing a**

base, such as, for example sodium hydroxide, to form an ionized compound, **sucrose** or sodium chloride **as tonicity agent**, for example, **the buffer** contains phosphate or **histidine**. **Co-solvents**, such as, for example, **polyethylene glycols, maybe added**. These water-based systems are effective at dissolving the compound of the invention and produce low toxicity upon systemic administration. The proportions of a solution system may be varied considerably, without destroying solubility and toxicity characteristics." (See page 13, paragraph 0137). It would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to incorporate various conventional pharmaceutical carriers (vehicles) such as PEG's, histidine, and sucrose within the injectable compositions taught by Jancso et al. based on the beneficial teachings provided by Guenzler-Pukall et al. which discloses that such conventional carrier (vehicles) are suitable therfor. The adjustment of particular conditions (e.g. determining appropriate amount ranges of carriers including PEG, histidine, and sucrose therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For the foregoing reasons given the instantly claimed invention is made obvious.

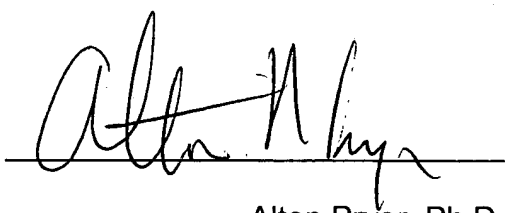
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616



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